PATENT **ATTORNEY DOCKET NO. DASI.002.03US**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jean-Michael Scherrman *et al.*	)	Examiner: Ponnaluri, Padmashri
Serial No.: 10/045,971	)	Art Unit: 1369
Filed: January 9, 2002	)	
Title: Cocaethylene immunogens and antibodies	)	**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Restriction Requirement mailed January 14, 2004, the deadline for responding having been extended by the attached Petition for Extension of Time and the requisite fee. The Examiner is respectfully requested to amend the above-identified application as indicated in the "Amendments to the Claims" set forth below.

Restriction Requirement begins on page 2 of this paper.

Response to Restriction Requirement begins on page 4 of this paper.

Traversal of Restriction Requirement begins on page 5 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 7 of this paper.

Remarks/Conclusion begin on page 10 of this paper.

CERTIFICATE OF FIRST CLASS MAILING

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Restriction/Election Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 13-15, drawn to a composition comprising hybridoma cell culture, classified in class 435, subclass 346.

Group II: Claim 16, drawn to a monoclonal antibody produced by a hybridoma cell (product-by-process claim), classified in class 530, subclass 389.1.

Group III: Claims 17-20, drawn to a hybridoma cell line, classified in class 435, subclass 346.

Group IV: Claims 21-22, drawn to a monoclonal antibody, classified in class 530, subclass 389.1.

Group V: Claims 23-26, drawn to a monoclonal antibody and a composition, classified in class 530, subclass 389.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, II, III, IV and V are all drawn to distinct products, which are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP (ss) 806.04, MPEP (ss) 808.01). Thus restriction between the groups is proper.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undo search burden, and restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A) If applicants elect either group, applicants are further requested to elect a single species

for each of the following:

a) a single species of hapten (cocaethylene comprises N-methyl tropane substituted at the para-position with a carboxyethyl group or a N-ethyl carboxmnide...)

b) a single species of linking group.

B) Further if group II is elected applicants are requested to elect a single species of antigenic protein.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds (or species), wherein each specific formula substituents of each of the above-identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependant form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP (ss) 809.02(a).

Response to the restriction requirement

Applicants hereby elect Group V (Claims 23-26) with traverse.

Applicants have read the Examiner's comments regarding an election of species and have concluded that this requirement applies only in the event that Applicants elect Group I or Group II ("If applicants elect either group") which contain the only claims that include the language referred to by the Examiner regarding the species of hapten and the linking group, plus the additional reference to Group II for further election of a single species of antigenic protein (*see* page 3, paragraphs A and B). Accordingly, Applicants have not made a species election.

Traversal of restriction requirement

Applicants traverse the Restriction Requirement because both criteria for a proper requirement for restriction have not been met for some of the Groups, namely (1) that the inventions must be independent or distinct as claimed and (2) there must be a serious burden on the Examiner if restriction is required (MPEP section 803). Applicants do not disagree with the Examiner's finding of five independent or distinct inventions, however in Applicants opinion it would not constitute a serious burden on the Examiner to examine at least some of the Groups together as set forth below, in particular Groups V, IV and II.

Option 1: Applicants have elected Group V (Claims 23-26). The Examiner has stated that the restriction is proper among the Groups that she has identified because "they have acquired a separate status in the art as shown by their different classification" *See* page 3, paragraph 3. In fact, each of Groups V, IV and II have an identical classification (class 530, subclass 389.1) and these inventions therefore have not acquired a separate status in the art. Furthermore, the Examiner states that for those groups that do have the same class/subclass classification, this would not affect the non patent literature search. Applicants respectfully disagree. To examine these Groups together will not constitute an undue burden whether the search is in the patent literature or the non-patent literature because the subject matter is the same, namely a monoclonal antibody which binds specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine. Indeed, the claims of Group V could be considered to be generic to those of Groups IV (Claims 21-22) and II (Claim 16). Accordingly the Examiner is respectfully requested to withdraw the restriction among these Groups and examine Groups V, IV, and II together.

Option II. For the reasons set forth above, to examine Groups V, IV, and II together will not constitute an undue burden whether the search is in the patent literature or the non-patent literature because the subject matter is the same, namely a monoclonal antibody which binds

specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine. The inventions of Groups I (Claims 13-15) and III (Claims 17-20) also have an identical classification (class 435, subclass 346) and these inventions therefore have not acquired a separate status in the art. Furthermore, as the Examiner has noted, Claim 13 is generic and can be considered to be generic not only for the claims of Group I, but also for the claims of Group III. Searching for hybridoma cell cultures that produce monoclonal antibodies which bind specifically to cocaine and cocaethylene and have low or no cross reactivity to benzoyl ecgonine will necessarily also identify the monoclonal antibodies themselves since the monoclonal antibodies cannot be made without hybridomas that produce the antibodies first being made and therefore it would not constitute an undue burden on the Examiner to examine all of the claims in this application together. The Examiner is therefore respectfully requested to withdraw the requirement for restriction and examine all of the Groups together.

Election of species: The Examiner has indicated that if Group I or II is elected (*see* discussion under "Response to Restriction Requirement" above) that applicants should additionally elect a species for examination of (a) hapten and (b) linking group (Group I or Group II) and also a species of antigenic protein (Group II). Accordingly, should the Examiner withdraw the requirement for restriction according to either Option 1 or Option II above, Applicants respectfully request that the requirement for election of a species be withdrawn because the subject matter of the claims is patentable. The hapten as recited in Claims 14 and 15 (Group I) and Claim 16 (Group II) has been patented (*see* USPN 6,114,508 Claims 1 and 6) as have antisera produced by immunizing a mammal using the hapten as recited in Claim 14 (*see* USPN 6,114,508 Claims 10 and 11). Likewise, the immunogen recited in Claim 14 (Group I) and Claim 16 (Group II) has been patented (*see* USPN 6,541,004 Claim 1). Since the haptens and the immunogens are patentable, then the monoclonal antibodies and hybridomas prepared using these patented materials also are patentable. The subject application is a continuation of the applications that issued as the '508 and '004 patents.